

## **REMARKS**

### **A. Background**

Claims 2 and 4-29 were pending in the application at the time of the Office Action. The Office Action objected to claims 4, 7, and 26 for various informalities. The Office Action rejected claims 4 and 10-18 for failing to comply with the written requirement. The Office Action rejected claims 4, 10, 11, 13-18, and 20-26 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action rejected claims 2, 4, 6-10, 19-21, 23-26, and 28-29 as being anticipated over cited prior art. Claims 5, 12-14, 18, and 27 were rejected as being obvious over cited prior art. By this response applicant has amended claims 2, 4, 7, 12, 19, 20, 24, 26, and 27; canceled claims 5, 16, and 17; and added new claims 30-31. As such, claims 2, 4, 6-15, and 18-31 are presented for the Examiner's consideration in light of the following remarks.

Applicant notes that a copy of a Revocation and Substitute Power of Attorney that was previously filed in the present application is again enclosed. Please direct all future communications accordingly.

### **B. Proposed Amendments**

The specification has been amended to clarify the reading thereof and to correct typographical errors. Applicant submits that the amendments to the specification do not introduce new matter and entry thereof is respectfully requested.

The drawings have been amended so as to clarify the views, place the drawings in a formal status, and to otherwise address formal issues in the drawings. Applicant respectfully

submits that the amendments to the drawings do not introduce new matter and entry thereof is respectfully requested.

By this response applicant has amended claims 2, 4, 7, 12, 19, 20, 24, 26, and 27; canceled claims 5, 16, and 17; and added new claims 30-31. Claims 7, 20, 24, and 26 have been amended to remedy various informalities or to clarify the claims. Claims 2, 4 and 19 have been amended to recite that the bone fixation element has an exterior surface with a thread thereon. Claims 4 and 19 have been amended to specifically recite when the crimp is attached while claim 12 has been amended to recite that the crimp is configured so as to prevent passage through the bore of the cannulated screw. New claims 30 and 31 relate to the configuration of the thread. Applicant respectfully submits that the amendments to the claims do not introduce new matter and entry thereof is respectfully requested.

C. Rejection on the Merits

Paragraph 5 of the Office Action objected to the drawings for not showing every feature of the invention. Specifically, the Office Action asserted that the drawings do not show the “‘endosteal guide’ having ‘an interior surface and an exterior surface, the interior surface bounding a channel extending through the endosteal guide such that the flexible filament may pass through the channel of the endosteal guide,’” as claimed in claim 16. Applicant has herein cancelled claim 16 so as to address the objection. As such, withdrawal of the objection is respectfully requested.

Paragraph 6 of the Office Action objected to claims 4, 7, and 26 for various informalities. Applicant has amended claims 4, 7, and 26 to remedy the objections, and respectfully requests that the objections to the claims be withdrawn.

***35 U.S.C. §112***

Paragraphs 7-8 of the Office Action rejected claims 4, 10, 11, and 12-18 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action objects to the crimp being selectively biased against the filament (claim 4), or the cannulated screw (claim 12). In particular, the Examiner appears to object to the word “selectively” used in claims 4 and 12. Applicant has amended claims 4 and 12 to remove the word “selectively” from both claims to remedy the rejection, and respectfully requests that the rejection to claims 4 and 12 under 35 U.S.C §112, first paragraph, be withdrawn. Claims 10, 11, and 13-18 were rejected for depending from claim 4 or 12. As such, in view of the amendments to claims 4 and 12, withdrawal of the rejections to claims 10, 11, and 13-18 is also respectfully requested.

Paragraphs 9-10 of the Office Action rejected claims 4, 10, 11, 12-18, and 20-26 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action alleges the phrase “selectively biased” is “vague and confusing” in claims 4 and 12. As mentioned above, Applicant has amended claims 4 and 12 to remove the word “selectively” from both claims. The Office Action also alleges that “the step of drilling” in claim 20 lacks antecedent basis. Applicant has amended claim 20 to remedy the rejection. Thus, Applicant respectfully requests that the rejection to claims 4, 12, and 20 under 35 U.S.C §112, second paragraph, be withdrawn. Claims 10, 11, 13-18, and 21-26 were rejected for depending from claim 4, 12, or 20. As such, in view of the amendments to claims 4, 12, or 20, withdrawal of the rejections to claims 10, 11, 13-18, and 21-26 is also respectfully requested.

***35 U.S.C. §102***

Paragraphs 11-12 of the Office Action rejected claims 2, 4, 6-9, 19-21, 23-26, and 28 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,773,910 to Chen et al. Of the rejected claims, claims 2, 4, and 19 are independent claims. As perhaps best depicted in Figure 4, Chen discloses a cruciate ligament prosthesis constructed using two separately tensionable strands 10, 11. On one end, the strands are connected to a cap-like device 12 which is held against the exterior surface of the first bone. The strands then pass through hard plastic sleeves 30, 31, 32, 33 inserted into tunnels in the bones and exit on the other end. Finally, the strands are secured to the exterior surface of the second bone using screws 14.

The Office Action asserts that the claimed “bone fixation element” reads on sleeves 30, 31, 32, and 33 of the Chen patent. As shown in Figure 4 of the Chen patent, the external surfaces of sleeves 30, 31, 32, and 33 are cylindrical and smooth. As such, applicant submits that the Chen patent does not disclose or suggest a **“bone fixation element comprising an exterior surface with a thread outwardly projecting therefrom,”** as recited in amended claims 2 and 4, or a **“bone fixation element having an outwardly projecting thread that engages the bone,”** as recited in amended claim 19. As will be discussed below in greater detail, applicant also asserts that it would not be obvious to form threads onto sleeves 30, 31, 32, and 33 as there is no motivation to do so.

Furthermore, the method of use of the Chen ligament is disclosed in column 4 of the Chen patent. Applicant asserts that the Chen patent does not disclose or suggest “said crimp being attached to the flexible filament **after** said graft ligament is positioned within said second bone tunnel,” as recited in claim 4 or “said crimp being secured onto the flexible filament **after**

the at least a portion of the flexible filament is disposed within the at least a portion of the tunnel,” as recited in claim 19.

Accordingly, since the Chen patent does not disclose all of the elements of claims 2, 4, or 19, claims 2, 4, and 19 cannot be anticipated by the Chen patent. Claims 6-9, 20-21, 23-26, and 28 depend from claims 2, 4, and 19, and thus incorporate the limitations thereof. As such, applicant submits that claims 6-9, 20-21, 23-26, and 28 are distinguished over the cited prior art for at least the same reasons as discussed above with regard to claims 2, 4, and 19.

Applicant also submits that many if not all of the dependent claims are also independently distinguishable over the cited prior art. For example, in Chen strands 10 and 11 form the artificial ligament. That is, no separate ligament is attached to strands 10 and 11. As such, the Chen clearly does not disclose or suggest **“attaching a graft ligament to said retaining means for holding a graft ligament,”** as recited in claim 10 or **“securing a ligament to the flexible filament,”** as recited in claim 29.

Paragraph 13 of the Office Action rejected claims 19-21, 28, and 29 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,456,721 to Legrand. Of the rejected claims, claim 19 is an independent claim. As perhaps best depicted in Figures 4 and 6, Legrand discloses a device for reinforcing a ligament transplant. The ligament is inserted into a knitted mesh sleeve 1 which is pulled through a head tube 5. The end of the mesh sleeve is gathered and inserted through a hole 53 in the end of the head tube and crimped (using crimp 7) or tied off. An insertion tube 6 is used to insert the head tube/ligament combination into place in a bone tunnel 40. Once in place, the insertion tube 6 is removed and ribs 54 and tabs 52 on the head tube spread out and hold the head tube in place in the bone tunnel.

As shown in Figures 4-6, the Legrand patent does not disclose or suggest threads on the head tube. Thus, the Legrand patent does not disclose or suggest a **“bone fixation element having an outwardly projecting thread that engages the bone,”** as recited in amended claim 19. Furthermore, because the head tube is inserted using insertion tube 6 so that ribs 54 and tabs 52 can radially spread out for attachment, there is no motivation to form threads on the head tube of Legrand. In addition, Legrand does not disclose or suggest **“said crimp being secured onto the flexible filament after the at least a portion of the flexible filament is disposed within the at least a portion of the tunnel,”** as recited in claim 19. Accordingly, since the Legrand patent does not disclose all of the elements of claim 19, claim 19 cannot be anticipated by the Legrand patent. Claims 20-21, 28, and 29 depend from claim 19 and thus incorporate the limitations thereof. As such, applicant submits that claims 20-21, 28, and 29 are distinguished over the cited prior art for at least the same reasons as discussed above with regard to claim 19.

Paragraph 14 of the Office Action rejected claims 2, 4, and 6-10 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,283,996 to Chervitz et al. Of the rejected claims, claims 2 and 4 are independent claims. As perhaps best depicted in Figures 7 and 8, Chervitz discloses a method and device for securing a ligament graft. A cable 46 formed from sutures 20 is attached to the bone end 22 of a ligament graft 21 and then pulled through a bone tunnel. After cable 46 exits the bone tunnel, a footing 48 is crimped onto the cable to hold the ligament graft in place.

The Office Action alleges that the bone end 22 of the ligament equates to a bone fixation element as claimed in the current invention. Applicant respectfully disagrees with this characterization. However, even assuming *arguendo* that bone end 22 of the ligament corresponds to the claimed bone fixation element, the Chervitz patent does not disclose or

suggest bone end 22 of the ligament having an exterior surface with threads projecting therefrom. Thus, the Chervitz patent does not disclose or suggest a **“bone fixation element comprising an exterior surface with a thread outwardly projecting therefrom,”** as recited in amended claims 2 and 4. Furthermore, because bone end 22 is secured within the tunnel by cable 46 and footing 48, there is no motivation to form threads on bone end 22.

Accordingly, since the Chervitz patent does not disclose all of the elements of claim 2 or 4, claims 2 and 4 cannot be anticipated by the Chervitz patent. Claims 6-10 depend from claim 2 or 4, and thus incorporate the limitations thereof. As such, applicant submits that claims 6-10 are distinguished over the cited prior art for at least the same reasons as discussed above with regard to claims 2 and 4.

Based on the above, therefore, Applicant respectfully requests that the rejection to claims 2, 4, 6-10, 19-21, 23-26, and 28-29 under 35 U.S.C §102 be withdrawn.

### ***35 U.S.C. §103***

Paragraphs 15-16 of the Office Action rejected claims 5, 12-14, 18, and 27 under 35 U.S.C. §103(a) as being unpatentable over the Chen patent. Specifically, the Office Action asserts that sleeves 30, 31, 32, and 33 correspond to the claimed “bone fixation element” and that it would have been obvious to modify the sleeves to have a thread outwardly projecting therefrom.

Applicant respectfully traverses the rejection. To establish a *prima facie* case of obviousness, among other things, the examiner must show a motivation to combine the elements. The Office action simply states that “it is well known in the art the use of cannulated bone screws in order to secure a ligament graft to a bone tunnel.” Applicant asserts that sleeves 30,

31, 32, and 33 are not used to “secure a ligament graft to a bone tunnel.” The Chen patent discloses that the “purpose of the plastic sleeve is to prevent excessive localized force being applied to the bone tunnel which might cause the location of the strands to move or drift in the bone.” Col. 3, lines 59-64. Thus, the purpose of the sleeves appears to be to uniformly distribute the load of the strands along the length of the tunnels.

Applicant respectfully submits that the Office Action fails to provide any disclosure that teaches or suggests any motivation for forming threads on sleeves 30, 31, 32, and 33 of the Chen patent where the sleeves are used for distributing load along the tunnel and do not relate to securing the ligament. In this regard, it may be preferable for the sleeves to be movable to enable adjustment for distributing the load. Furthermore, forming threads on sleeves 30, 31, 32, and 33 would necessitate that the sleeves be screwed into the tunnels which would require more time and effort to complete the surgical procedure, thereby providing motivation against adding the threads. As such, applicant submits that the Office Action fails to establish a proper *prima facie* rejection with regard to claims 5, 12-14, 18, and 27. (It is noted that claim 5 has been cancelled and that the limitations thereof have been incorporated into claim 2.) As such, withdrawal of the rejections is respectfully requested.

No other objections or rejections are raised in the Office Action.

D. Conclusion

Applicant notes that this response does not discuss every reason why the claims of the present application are distinguished over the cited prior art. Most notably, applicant submits that many if not all of the dependent claims are independently distinguishable over the cited prior

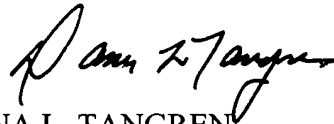


art. Applicant has merely submitted those arguments which it considers sufficient to clearly distinguish the claims over the cited prior art.

In view of the foregoing, Applicant respectfully requests the Examiner's reconsideration and allowance of claims 2, 4, 6-15, and 18-31 as amended and presented herein. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 31 day of May 2005.

Respectfully submitted,



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### **DRAWING AMENDMENTS**

The present application was filed with informal drawings containing Figures 1-21 on 21 sheets of drawings. Please replace the original filed informal drawings with the attached formal replacement drawings containing Figures 1-21 on 20 sheets of drawings. Also enclosed are annotated sheets where amendments to the replacement drawings relative to the original drawings have been noted.

Attachment: Replacement Drawings

Annotated Drawings